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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,833	09/30/2003	Leslie J. Charles	57072US037	6896

32692 7590 05/14/2004

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EXAMINER	
HUANG, EVELYN MEI	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,833	CHARLES ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 53-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 53-57 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 53-57 are pending. Claims 1-52 have been canceled according to the preliminary amendment filed on 9-30-2003.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. ***.

a. *Nature of the invention.*

The instant invention is drawn to a heterocyclic ether substituted imidazoquinoline for treating a neoplastic disease in an animal.

b. *State of the prior art and the level of the skill in the art.*

Iimidazo[4,5-c]quinolin-4-amine derivatives are known (Gerster I, 5266575, PTO-1449, columns 9-10). Certain imidazo[4,5-c] quinoline compounds have been shown to induce TNF and IL-1 production (Testerman, PTO-1449, abstract). Although interferon alpha has been implicated in many diseases, including neoplastic diseases, a nexus between the induction of interferon biosynthesis and the treatment of these diseases has not been fully established. Furthermore, at present there is no known umbrella drug that can treat any type of neoplastic diseases, since the different neoplastic diseases are of different origins, have different cellular mechanisms and consequently, would require different treatment protocols.

The level of the skill in the anticancer art is high.

c. *Predictability/unpredictability of the art.*

The high degree of unpredictability is well-recognized in the anticancer art. For example, some drugs known to be effective against small cell lung cancer are inactive in melanoma (Sof'ina et al. Experimental Evaluation of Antitumor Drugs in the USA and USSR and Clinical Correlations. NCI Monograph 55. NIH Publication No. 80-1933 (1980), page 77). The 1, 3-cyclohexanediones shown to be active in test against human sarcoma is found to be inactive against other types of cancer such as leukemia, lymphoscarcoma etc. (Strandtmann, J. Med. Chem. (1967), 10(6):1063-1065). Correlation between the anti-tumor drugs in experimental system and in patient treatment is incomplete (Sof'ina, page 76). Furthermore, it is known that a slight change in the structure of the compound would drastically change its biological activity as evidenced in the very different ED_{50} values for the structurally similar compounds (Strandtmann, page 1065, Table II). One of ordinary skill in the art therefore would have little basis to extrapolate the data from one sets of compounds to other structurally dissimilar compounds.

d. *Amount of guidance/working examples.*

The preparation of 37 example compounds has been described. Compounds having aryl, heteroaryl, heterocyclyl, further substituted with optionally substituted aryl, heteroaryl, heterocyclyl have not been exemplified.

The ability of the example compounds to induce interferon and TNF in human blood cells is shown on pages 96-98 of the specification. The procedures for assessment of the anti-neoplastic activity are not described. No in vivo procedures are described.

e. *Breadth of the claims.*

Applicant's assertion that all the structurally diverse compounds, including those having aryl, heteroaryl, heterocyclyl, further substituted with optionally substituted aryl, heteroaryl, heterocyclyl, are effective in treating any or all neoplastic diseases does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the anti-cancer art, the working examples limiting to induction of interferon alpha and TNF, and the fact that at present there is no known umbrella drug effective for treating all types of neoplastic diseases (paragraphs c, d above).

f. *Quantitation of undue experimentation.*

Since insufficient guidance and teaching have been provided by the specification (paragraphs c-e above), one of ordinary skill in the art, even with high level of skill, is unable to use all the compounds as claimed without undue experimentation.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 53-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49, 51, 53, 55, 57 of U. S. Patent No. 6664260. The patented method comprising administering the patented compound to the animal having a neoplastic disease is embraced by the instant method of treating a neoplastic disease with the same compound.

5. Claims 53, 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 25 of U. S. Patent No. 6656938 or U. S. Patent No. 6660735 (CIP of 6656938) The patented method comprising administering the patented compound wherein R4 and R8 together form a piperidinyl (exemplified in Examples 22-25) to the animal having a neoplastic disease is embraced by the instant method of treating a neoplastic disease with the instant compound (wherein R1 is heterocyclyl or R4-heterocyclyl, the heterocyclyl being substituted).

6. Claims 53, 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 26 of U. S. Patent No. 6683088 or U. S. Patent No. 6677347 (CIP of 6683088) The patented method comprising administering the inventive compound wherein R4 and R3 together form a piperidinyl (exemplified in Examples 27-29) to the animal having a neoplastic disease is embraced by the instant method of treating a neoplastic disease with the instant compound (wherein R1 is heterocyclyl or R4-heterocyclyl, the heterocyclyl being substituted).

7. Claims 53, 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 26 of U. S. Patent No. 6660747 or claims 26, 28 of U. S. Patent No. 6664256 (CIP of 6660747) The patented method comprising administering the inventive compound wherein R4 and R7 together form a piperidinyl (exemplified in Examples 35-38) to the animal having a neoplastic disease is embraced by the instant method of treating a neoplastic disease with the instant compound (wherein R1 is heterocyclyl or R4-heterocyclyl, the heterocyclyl being substituted).

8. Claims 53, 56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25 of copending Application No. 10/680898 or claims 26, 27 of copending Application No. 10/681814. Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending method of treating a neoplastic disease with the copending compound wherein R4 and R8 together form a piperidinyl (exemplified in Examples 22-25) is embraced by the instant method of treating a neoplastic disease with the instant compound (wherein R1 is heterocyclyl or R4-heterocyclyl, the heterocyclyl being substituted).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 53, 56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28, 29 of copending Application No. 10/681711 or copending Application No. 10/681457. Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending method of treating a neoplastic disease with the copending compound wherein R4 and R7 together form a piperidinyl (exemplified in Examples 35-38) is embraced by the instant method of treating a neoplastic disease with the instant compound (wherein R1 is heterocyclyl or R4-heterocyclyl, the heterocyclyl being substituted).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 53, 56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 21 of copending Application No. 10/696476 or copending Application No. 10/696478. Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending method of treating a neoplastic disease with the copending compound wherein R4 and R3 together form a piperidinyl (exemplified in Examples 27-29) is embraced by the instant method of treating a neoplastic disease with the instant compound (wherein R1 is heterocyclyl or R4-heterocyclyl, the heterocyclyl being substituted).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
Primary Examiner
Art Unit 1625

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